

Appl. NO. 09/040,111  
Amendment dated: April 9, 2004  
Reply to OA of: December 9, 2003

This listing of claims will replace all prior versions and listings of claims in the application.

**Listing of Claims:**

Claims 1-41 (canceled).

42(currently amended). A crystallisation process for lactose or lactose monohydrate comprising:

- D.K.  
to enter  
S.T.  
4/27/04
- a) dissolving ~~the substance to be crystallised~~ lactose or lactose monohydrate in an aqueous solution of a Carbomer;
  - b) applying a means for adjusting the viscosity of the aqueous solution of a Carbomer until a gel with an apparent viscosity in the range 25 to 90 Pa.s at a shear rate of  $1s^{-1}$  is reached;
  - c) allowing crystal growth;
  - d) applying a means for adjusting the viscosity of the aqueous solution of a Carbomer until a fluid with an apparent viscosity less than 25 Pa.s at a shear rate of  $1s^{-1}$  is reached; and
  - e) harvesting the crystals.

43(currently amended). A crystallisation process as claimed in claim 42, wherein the means for adjusting the viscosity of the ~~medium~~ aqueous solution of a Carbomer is temperature change, ultrasound, thixotropicity, electro-rheology, mechanical shear, chemical additive, or pH change.

44(currently amended). A crystallisation process as claimed in claim 43, wherein the means for adjusting the viscosity of the ~~medium~~ aqueous solution of a Carbomer is pH change.

Appl. No. 09/046,111  
Amendment dated: April 9, 2004  
Reply to OA of: December 9, 2003

45(previously presented). A crystallisation process as claimed in claim 42, wherein the crystals are harvested by means of collection by filtration.

46(currently amended). A crystallisation process as claimed in claim 42, wherein the process comprises:

- a) dissolving ~~the substance~~ lactose or lactose monohydrate to be crystallised in an aqueous solution of a Carbomer wherein the viscosity of the medium is pH-dependent;
- b) adjusting the pH of the aqueous solution of a Carbomer until a gel with an apparent viscosity in the range 25 to 90 Pa.s at a shear rate of  $1\text{s}^{-1}$  is reached;
- c) allowing crystal growth;
- d) adjusting the pH of the aqueous solution of a Carbomer until a fluid with an apparent viscosity less than 25 Pa.s at a shear rate of  $1\text{s}^{-1}$  is reached;  
and
- e) harvesting the crystals.

47(previously presented). Lactose monohydrate crystals obtained according to the process as claimed in claim 42.

48(previously presented). A pharmaceutical formulation for administration by inhalation comprising lactose monohydrate crystals as claimed in claim 47.

49(previously presented). A pharmaceutical formulation for administration by inhalation comprising lactose monohydrate crystals as claimed in claim 47 and/or fluticasone propionate or salmeterol xinafoate crystals.

50(currently amended). A crystallisation process as claimed in claim 42, wherein the ~~substance to be crystallised is lactose monohydrate and the~~ crystallised lactose

App. No. 09/040, 111

Amendment dated: April 9, 2004

Reply to OA of: December 9, 2003

monohydrate has an elongation ratio of  $1.58 \pm 0.33$  and a size in the range of 63 to 90  $\mu\text{m}$ .

51(previously presented). A lactose monohydrate according to claim 47, having an elongation ratio  $1.58 \pm 0.33$  and a size in the range of 63 to 90  $\mu\text{m}$ .

52(previously presented). Lactose monohydrate according to claim 47, having an elongation ratio of from 1.55 -2.20.